



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,842	04/10/97	KAESEMEYER	W 97-092-US

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HM42/1118

EXAMINER

JONES, D

ART UNIT	PAPER NUMBER
1614	9

DATE MAILED: 11/18/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. <b>08/833,842</b>	Applicant(s) <b>Kaesermeyer</b>
Examiner <b>Dwayne C. Jones</b>	Group Art Unit <b>1614</b>

Responsive to communication(s) filed on 3 Sep 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-11 and 13-19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-11 and 13-19 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-11 and 13-19 are pending.
2. Claims 1-11 and 13-19 are rejected.

### ***Information Disclosure Statement***

3. The Information Disclosure Statement filed September 3, 1998 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

### ***Claim Irregularities***

4. It is noted that claim 10 is missing the capital letter of "T" at the begining of the claim.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claims 1-11 and 13-19 rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Cooke et al. in view of Pitt et al is hereby maintained for both the

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above-stated and the following reasons. Cooke et al. teach that the oral administration of arginine improves endothelium-dependent vasorelaxation which is associated with a reduction in atherogenesis, (see abstract). Pitt et al. teach that pravastatin reduces the progression of coronary atherosclerosis, (see abstract). Both of these prior art references teach the skilled artisan of the reduction of atherosclerosis with the administration of arginine and pravastatin. Accordingly, it would have been obvious to one having ordinary skill in the art to combine the administration of arginine and pravastatin in order to combat the deleterious effects or reduce the atherosclerosis.

#### *Response to Arguments*

7. Applicant's arguments filed September 3, 1998 have been fully considered but they are not persuasive. Applicant argues that neither of the prior art references of Cooke et al. nor Pitt et al. provide any motivation to combine L-arginine and pravastatin.
8. Responding to applicant's argument that the prior art references of Cooke et al. nor Pitt et al. provide any motivation to combine L-arginine and pravastatin, Pitt et al. specifically teach the skilled artisan that multiple drug regimens are used to treat atherosclerosis, (see column 1, page 1138, paragraph 4). Pitt et al. also state that patients with elevated serum LDL cholesterol levels should be placed on an effective diet and drug therapy, preferably a reductase inhibitor. Pitt et al. further teach that a Mediterranean diet and life-style changes might be more desirable than pharmacologic lipid-lowering therapy alone, (as cited from column 1, page 1138, last paragraph). Pitt et al. further teach that pravastatin can treat coronary artery disease. With these two

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teachings, one having ordinary skill in the art is provided with the motivation to combine more than one drug to treat atherosclerosis progression, particularly pravastatin with L-arginine.

Cooke et al. teaches the skilled artisan that the administration of L-arginine decreases atherosclerosis, by improving vasorelaxation. The administration of L-arginine can be through dietary supplementation, (see abstract). And so it would have been obvious to skilled artisan to coadminister pravastatin with L-arginine, especially since the prior art reference of Pitt et al. teaches that multiple drug regimens are used to treat atherosclerosis.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to D C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
D.C. Jones

November 13, 1998